

U.S.S.N. 09/621,092

Filed: July 21, 2000

**AMENDMENT AND RESPONSE TO OFFICE ACTION****Remarks**

Claims 28-30, 41 and 43-45 are pending. Claim 41 has been amended as discussed below.

**Rejection Under 35 U.S.C. § 102**

Claims 30, 41, and 43-45 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,632,971 to Yang. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

***U.S. Patent No. 5,632,971 to Yang***

Yang describes an empty medicinal capsule including a cap member containing a cap circumferential slot (3') and at least one raised member disposed on the inner surface thereof, and a body member containing a body circumferential slot (3), whereby the cap member circumferential slot and the body member circumferential slot can be slidably locked with each other (abstract). A plurality of raised triangular slots (7) formed on the inner surface of the cap member prevent final locking of the capsule when in a prelocking state (col. 3, lines 32-38) and prevent the separation of the cap and body members once the capsule is in a final locking state (col. 4, lines 4-12). Yang discloses a medicament capsule with raised members and slots which orient the top portion of the capsule with the bottom portion of the capsule. Yang does not suggest the use of this capsule in an inhaler which is specifically fitted for the medicament capsule. Yang mentions that the cap and body member should be aligned so that the label printed on the capsule is in alignment, but does not suggest that this label is placed on the keying surface (col. 2, lines 13-16).

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Claim 41 defines a capsule (1) to contain drug for use in an inhaler comprising (2) at least one keying surface on an outside surface of a distal end of the capsule that is (a) adapted to orient the capsule within the inhaler or (b) identifies the drug to be placed in the capsule. Claim 41 has been amended to include a feature specific for use in an inhaler, the feature of at least one hole allowing air (or other gas) to enter in, through, and out of the capsule, thereby providing a means for delivery of the medicament. Support for this amendment is found at page 10, lines 4-15. Claim 30 defines the capsule of claim 41 further including a medicament.

The Examiner considers slots 3' and 7 to be keying surfaces. As discussed above, cap circumferential slot (3') and raised triangular slots (7) are not mechanisms to orient the capsule within an inhaler, but rather means for locking the top portion of the capsule to the bottom portion of the capsule (col. 4, lines 4-12). Furthermore, slots 3' and 7 are clearly not located in the same location as disclosed in the present invention. Claim 41 has been amended to clarify that the keying surfaces are found on the outside surface of the distal ends of the capsule. Support for this amendment can be found on page 11, lines 14-18 and in Figures 7 and 18.

The capsule described by Yang is clearly *structurally different* from the claimed capsule. Slots 3' and 7 as described by Yang are near the closed ends of the capsule, but are not located on the distal ends (e.g., the top and bottom of the capsule). The capsule of Yang would, if placed in an inhaler, orient within the inhaler differently than the claimed capsule. Furthermore, there is no suggestion that the cap circumferential slot (3') or raised triangular slots (7) could be moved to the distal ends of the capsule, while still maintaining the locking mechanism of the capsule claimed by Yang. In response to the Examiner's comment that the inhaler is not positively

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recited, please note that both claim 41 and claim 42 recite the functional limitation that the keying surface is 'adapted to orient the capsule within the inhaler.' MPEP § 2173.05(g) explains that "[a] functional limitation is an attempt to define something by what it does, rather than by what it is. There is nothing inherently wrong with defining some part of an invention in functional terms." In this case, the keying surface must specifically fit the inhaler corresponding to the particular medicament capsule, such that it orients the capsule within the inhaler.

There is no disclosure at all of a hole in the capsule to allow air into and out of the capsule, allowing the capsule to be used in an inhaler. Indeed, Yang teaches away from such a capsule by emphasizing the need for the capsule to lock and seal.

Therefore, Yang does not anticipate claims 30 and 41.

Claim 43 defines the capsule of claim 41 wherein the keying surface is adapted to orient the capsule within the inhaler. Claim 44 defines the capsule of claim 41 wherein the keying surface identifies the drug to be placed in the capsule. Claim 45 defines the capsule of claim 41 comprising a keying surface on the outside of one end which is adapted to orient the capsule within the inhaler and a keying surface on the outside of the other end which identifies the drug to be placed in the capsule.

As discussed above, Yang does not disclose the use of keying surfaces to orient the capsule within the inhaler as in claim 43. Furthermore, the keying surfaces are not located on the distal ends of the capsule. Yang does not disclose a capsule wherein the *keying surface* identifies the drug to be placed in the capsule as in claims 44 and 45. Yang discusses placing a label on the

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*body member* of the capsule (col. 2, lines 13-16), not on a keying surface on a distal end of the capsule. Therefore, Yang cannot anticipate claims 43-45.

Allowance of claims 28-30, 41 and 43-45 is respectfully solicited.

Respectfully submitted,



Patrea J. Pabst  
Reg. No. 31,284

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HOLLAND & KNIGHT LLP  
One Atlantic Center, Suite 2000  
1201 West Peachtree Street  
Atlanta, Georgia 30309-3400  
(404) 817-8473  
(404) 817-8588 (Fax)

**Certificate of Facsimile Transmission**

I hereby certify that this Amendment and Response to Office Action, and any documents referred to as attached therein are being facsimile transmitted on this date, January 16, 2004, to the Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.



Patrea Pabst

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